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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,393	03/10/2004	Hans Sejr Olsen	10391.200-US	4566
25908 7590 08/17/2007 NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			EXAMINER HA, JULIE	
			ART UNIT 1654	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,393	Applicant(s) OLSEN ET AL.	
	Examiner Julie Ha	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 97-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 97-149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment After Non-Final Rejection filed on July 10, 2007 is acknowledged. Claims 39-96 have been cancelled and new claims 97-149 have been added. Claims 97-149 are pending in this application. An Election/Restriction requirement was mailed out on September 28, 2006. Applicants elected Group I (claims 38-89 and 91-96) drawn to a method for producing alcohol, without traverse because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, filed on November 28, 2006. A Non-Final Rejection was mailed out on February 23, 2007. Claims 97-149 are examined on the merits in this office action.

Withdrawn Objection and Rejections

1. All objections recited in the previous office action are hereby withdrawn due to Applicants' amendments.
2. All rejections not recited herein are hereby withdrawn due to Applicants' amendments.

Maintained Rejections

35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 97-98, 101-118, 123-127, 134-135 and 138-149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen et al (US Patent # 4316956) in view of Yoshizumi et al (US Patent # 4092434).

7. The instant claims are drawn to a process for production of an alcohol product comprising the sequential steps of: (a) holding a slurry comprising water and granular starch in the presence of an acid alpha-amylase and a glucoamylase at a temperature of 0°C to 20°C below the initial gelatinization temperature of the granular starch for a period between 20 minutes and 1.5 hours, and (b) fermenting the slurry in the presence

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of an acid alpha-amylase, a glucoamylase and a yeast at a temperature between 10°C to 35°C to produce the alcohol product, and recovering the alcohol product. The claims are further drawn to different temperatures for step (a), different pHs during steps (a) and (b), different time points for step (a), and wherein the acid alpha-amylase is an acid bacterial alpha-amylase.

8. As described in the previous office action, Lutzen et al teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). The reference teaches that pH optimum for the ethanol producing microorganism is pH 3-7, 25°C to 38°C (see column 5, lines 37-40). Alpha amylase (*B. licheniformis*) and glucoamylase are added, and the suspension stirred on a water bath for 18 hours at 60°C, and the slurry are transferred to a fermentation flask cooled to 30°C and to the flask are added: yeast extract solution, antibiotics, yeast suspension, and glucoamylase, and the fermentation is conducted at 30°C for 6 days (see columns 11 and 12, Example 1). The reference teaches the dosage range for alpha-amylase is 0.02 to 2.0 FAU/g of starch, preferably 0.05-0.6 FAU/g (see column 6, lines 54-57) and the glucoamylase dosage of 0.05 to 10.0 AGU/g of starch, preferably 0.2 to 2.0 AGU/g starch (see column 5, lines 59-61). Additionally, Example 1 teaches using 65 µl alpha-amylase to 135 µl of glucoamylase (see column 11, Example 1). This reads on claims 123 and 124. The reference further teaches that the fermentation of a granular starch slurry having 25-40% starch by weight (see column 8, lines 15-17). This reads on claims 116-118. The reference is silent regarding the pH range of step (b). However, it is obvious to assume that since

the pH was adjusted to pH 5 (see column 11, line 66) and 98% sulfuric acid was present in the fermentation trap (see column 12, lines 14-16), it would have been obvious to optimize using sulfuric acid to get the optimal pH of the reaction absent any critical limitation (see paragraph 18 below). The reference is silent as to recovering the alcohol product. However, it is obvious to assume that since the reference teaches the fermentative production of ethanol, it would have been obvious to recover the ethanol. The difference between the reference and the instant claim is that the reference does not teach the step (a) from 5 minutes to 1.5 hours.

9. However, Yoshizumi et al (US Patent # 4092434) teach that method for manufacturing alcohol or alcohol beverage which, by avoiding the high-temperature, high-pressure cooking step of the prior art, saves energy to be used and the amount of cooling water, and which eliminates a danger in operation that stems from the operation using a high temperature and high pressure, and which lowers construction and maintenance costs of the equipment by the alteration from high pressure equipment to atmospheric pressure equipment (see column 1, lines 61-68 and column 2, lines 1-3).

10. Therefore, it would have been obvious to the ordinary skilled in the art to optimize the processing conditions of Yoshizumi et al on the teachings of Lutzen NW. There is a reasonable expectation of success since Yoshizumi et al teach that by avoiding the high-temperature, high-pressure step would save energy, and eliminates a danger in operating at high temperature and pressure. By optimizing the reaction condition by increasing the temperature, the reaction time would be decreased. There is a reasonable expectation of success since MPEP states the following: Generally,

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differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). There is reasonable expectation of success since “The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine

where in a disclosed set of percentage ranges is the optimum combination of percentages."

Response to Applicant's Arguments

11. Applicant argues that Lutzen does not teach or suggest a pretreatment step for a period between 20 minutes to 1.5 hours as claimed. Applicant argues that Lutzen et al teach pretreatment step in which the starch slurry is treated with an alpha-amylase and a glucoamylase at temperatures below the initial gelatinization temperature for up to 20 hours at from 30°C to 60°C will serve to hasten the commencement of fermentative generation of ethanol in the fermentor; the examples include a pretreatment step holding time of at least 3 hours (see Example 2), 3-20 hours (see Example 6), and 4.5 hours (see Example 4). The Applicant further argues that Yoshizumi et al disclose a process for producing an alcohol comprising cooking mash of cereal grains and liquefying enzymes at a temperature of from 75-85°C, saccharification, and fermentation with yeast, and since the prior art teach temperature above the initial gelatinization temperature of the starch, the starch is partially gelatinized prior to saccharification and fermentation.

12. Applicant's arguments have been considered but have not been found persuasive because, Lutzen et al disclose the pretreatment steps and teach that temperatures below the initial gelatinization temperature for up to 20 hours will serve to hasten the commencement of fermentative generation of ethanol. Furthermore, the Lutzen patent discloses examples of pretreatment at several different time points.

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Additionally, as described above, Yoshizumi et al teach that method for manufacturing alcohol or alcohol beverage which, by avoiding the high-temperature, high-pressure cooking step of the prior art, saves energy to be used and the amount of cooling water, and which eliminates a danger in operation that stems from the operation using a high temperature and high pressure, and which lowers construction and maintenance costs of the equipment by the alteration from high pressure equipment to atmospheric pressure equipment. Therefore, it would have been obvious to the ordinary skilled in the art to optimize the processing conditions of Yoshizumi et al on the teachings of Lutzen NW. There is a reasonable expectation of success since Yoshizumi et al teach that by avoiding the high-temperature, high-pressure step would save energy, and eliminates a danger in operating at high temperature and pressure. By optimizing the reaction condition by increasing the temperature, the reaction time would be decreased.

13. Furthermore, it has been held that under KSR that "obvious to try" may be an appropriate test under 103. The Supreme Court stated in KSR, When there is motivation "to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, __, 82 USPQ2d 1385, 1397 (2007).

14. The "problem" facing those in the art was completely converting starch into fermentable sugars, and even relatively minor deficiencies in conversion of starch into

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the fermentable maltose and glucose have adverse affect on the fermentation, the least of which is lower yield and greater process expense, and there were a limited number of methodologies available to do so, for example starch liquefaction and hydrolysis procedures capable of producing a pure glucose syrup followed by saccharification, and this requires moderate to large quantities of thermal energy (see Lutzen patent '956, column 1, lines 23-48). Furthermore, Lutzen patent teaches that the fermentation may be carried out on a slurry of solid and completely ungelled starch, i.e., granular starch, dosed with alpha-amylase and glucoamylase. During this course of the fermentation, the starch is enzymatically liquefied and saccharified into fermentable sugars and the sugars are fermented. Control over the fermentation rate is possible through variations in the starch concentration in the slurry, by pre-conditioning of the starch, and though variations in the concentration and proportions of the enzymes (see column 2, lines 13-25). Furthermore, the Lutzen patent teaches different time points of up to 20 hours of pretreatment. The skilled artisan would have had reason to try these methodologies with the reasonable expectation that at least one would be successful. Different time points for pretreatment, different pretreatment temperatures, different pH and different concentrations of slurry and enzyme would have been tried for production of alcohol. Thus, holding a slurry of granular starch in the presence of an acid alpha-amylase (different concentrations) and glucoamylase (different concentrations) at different temperatures and time points for pretreatment of the slurry and fermenting the slurry in the presence of the enzymes to produce the alcohol product is a "the product not of

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innovation but of ordinary skill and common sense," leading to the conclusion that invention is not patentable as it would have been obvious.

15. Claims 97-100, 116-122, 128-130, 132-133, 137 and 138-149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen NW (US Patent # 4316956) in view of Lantero et al (US Patent # 5231017).

16. The instant claims are drawn to a process for production of an alcohol product (fuel) comprising the sequential steps of (a) providing a slurry comprising water and granular starch, holding said slurry (5-60% DS granular) in the presence of an acid alpha amylase and a glucoamylase at a temperature of 0°C to 20°C below the initial gelatinization temperature of said granular starch for a period of 5 minutes to 1.5 hours, (b) fermenting the slurry in the presence of an acid alpha amylase and a glucoamylase and a yeast at a temperature between 10°C to 35°C to produce ethanol and an enzyme activity xylanase or cellulose for a period of 5 to 190 hours, and recovering the ethanol and the acid alpha amylase is an acid fungal alpha amylase obtained from *Aspergillus niger* or *Aspergillus oryzae* and glucoamylase is obtained from *Aspergillus niger*. The claim is also drawn to the alcohol product is a beer.

17. As described in paragraph 8, Lutzen teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). Furthermore, the reference teaches that the addition of the alpha amylase from *Aspergillus oryzae* saccharifies dextrins to maltotriose and maltose. The reference teaches that although the purpose of the alpha

amylase is to liquefy the starch, its saccharification propensity also make the alpha amylase some part of the saccharifying enzyme content (see column 6, lines 7-14). The reference further teaches that the traditional process for making beer wherein grains are hydrolyzed by malt results in a wort with a significant nonfermentable polysaccharide content, and, in turn, a beer with a significant polysaccharide content (see column 1, lines 32-36). The reference also teaches the solids content of a wet mill starch slurry is close to 40% starch by weight (see column 11, lines 9-11). The difference between the reference and the instant claims is that the reference does not teach acid fungal alpha amylase from *Aspergillus niger* and glucoamylase obtained from *Aspergillus niger*.

18. However, Lantero et al (US Patent #5231017) teach a process for producing ethanol from raw materials containing a high dry solids mash level, and that contain fermentable sugars or constituents which can be converted into sugars, comprising steps (a) liquefaction, (b) saccharification, (c) fermentation, and (d) recovering the ethanol (see column 1, lines 49-65). The reference also teaches that it may also be advantageous to add some enzymes to the liquefied mash during saccharification and/or during fermentation. Examples of such enzymes are cellulases, hemicellulases, phosphatase, exo- and endoglucanases, and xylanase (see column 3, lines 65-68 to column 4, lines 1-2). This reads on claim 61. Furthermore, the reference teaches that in commercial fuel alcohol production, the liquefied whole corn mash is diluted with thin stillage prior to fermentation (see column 6, Example 4). Additionally, the reference teaches the acid fungal protease is derived from *Aspergillus niger* (see column 2, lines 15-27). The reference further teaches that the steps of saccharification and the

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fermentation steps are carried out either simultaneously or separately, preferably the saccharification and fermentation steps are carried out simultaneously. When carried out simultaneously, the glucoamylase derived from *Aspergillus niger* and the acid fungal protease derived from *Aspergillus niger* can be introduced as a single mixture composition, sold by Solvay Enzymes, Inc. (see column 3, lines 44-54). Additionally, results obtained from the simultaneous saccharification and fermentation of whole corn mash with the addition of acid fungal protease (AFP) increased the rate and level of ethanol obtained. The reaction without AFP present, more glucose remained unfermented (see column 5, lines 28-36). The reference further teaches that liquefied corn mash containing glucoamylase and inoculated with yeast, fermentation are conducted for 60 hours (see column 8, Example 10). Furthermore, the reference teaches whole ground corn was liquefied, fermentation flasks were prepared as in Example 1, except the mash DS was adjusted to 27.76% DS (w/w) (see column 10, lines 1-4). The reference further discloses the process wherein the raw materials are whole ground corns, cobs, corns, grains, milo or cereals (see Claim 4).

19. Therefore, it would have been obvious to the ordinary skilled in the art to combine the use of acid fungal alpha amylase from *Aspergillus (niger or oryzae)* since the two strains are from the same genus and both glucoamylase and acid fungal amylase can be obtained from the *Aspergillus* strains (see Lantero Patent, column 3, lines 50-54). There is a reasonable expectation of success since carrying out the saccharification and the fermentation steps using the glucoamylase and acid fungal alpha amylase together increased the rate and the level of ethanol obtained. Although

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the Lantero reference is silent in regards to holding time under step b) from 10 minutes to 6 hours and step c) for a period of 70 to 140 hours and 80 to 130 hours, it would be obvious to optimize to acquire through routine experimentation to obtain the optimal levels absent and critical (see paragraph 18). The skilled artisans motivation is to optimize the production of the product, with less time and less effort.

Response to Applicant's Arguments

20. Applicant argues that Lutzen does not teach or suggest a pretreatment step for a period between 20 minutes to 1.5 hours. Applicants further argue that Lantero et al disclose a process for producing ethanol comprising liquefaction, saccharification, and fermentation, wherein a protease is introduced during saccharification and/or fermentation. Lantero patent teaches liquefaction step at a temperature above the initial gelatinization temperature of the starch, the starch is gelatinized prior to saccharification and fermentation.

21. Applicant's arguments have been considered but have not been found persuasive because Lutzen et al disclose the pretreatment steps and teach that temperatures below the initial gelatinization temperature for up to 20 hours will serve to hasten the commencement of fermentative generation of ethanol. Furthermore, the Lutzen patent discloses examples of pretreatment at several different time points. Lantero et al teach the process for producing ethanol (commercial fuel alcohol production), using the standard alcohol production steps (liquefaction, saccharification, fermentation, and recovering ethanol). Lantero teaches alpha-amylase in liquefaction

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step and the use of glucoamylase in saccharification step. Furthermore, the Lantero patent discloses that the steps of saccharification and the fermentation steps are carried out either simultaneously or separately, preferably the saccharification and fermentation steps are carried out simultaneously. The liquefaction step consists of alpha-amylase, thus the liquefied mash would have alpha-amylase present, and having the saccharification and fermentation steps can be carried out simultaneously, the starch mash would have both the alpha-amylase and glucoamylase and yeast and the proteases claimed in the instant claim during the fermentation process.

22. As described above, it has been held that under KSR that "obvious to try" may be an appropriate test under 103. The Supreme Court stated in KSR, When there is motivation "to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, __, 82 USPQ2d 1385, 1397 (2007).

23. The "problem" facing those in the art was completely converting starch into fermentable sugars, and even relatively minor deficiencies in conversion of starch into the fermentable maltose and glucose have adverse affect on the fermentation, the least of which is lower yield and greater process expense, and there were a limited number of methodologies available to do so, for example starch liquefaction and hydrolysis procedures capable of producing a pure glucose syrup followed by saccharification, and

this requires moderate to large quantities of thermal energy (see Lutzen patent '956, column 1, lines 23-48). Furthermore, Lutzen patent teaches that the fermentation may be carried out on a slurry of solid and completely ungelled starch, i.e., granular starch, dosed with alpha-amylase and glucoamylase. During this course of the fermentation, the starch is enzymatically liquefied and saccharified into fermentable sugars and the sugars are fermented. Control over the fermentation rate is possible through variations in the starch concentration in the slurry, by pre-conditioning of the starch, and through variations in the concentration and proportions of the enzymes (see column 2, lines 13-25). Furthermore, the Lutzen patent teaches different time points of up to 20 hours of pretreatment. Lantero et al discloses that the addition of protease to mash has been shown to increase amino nitrogen sufficient to support accelerated rates of ethanol fermentation (see column 1, lines 12-15). The skilled artisan would have had reason to try these methodologies with the reasonable expectation that at least one would be successful. Different time points for pretreatment, different pretreatment temperatures, different pH and different concentrations of slurry and enzyme would have been tried for production of alcohol. Thus, holding a slurry of granular starch in the presence of an acid alpha-amylase (different concentrations) and glucoamylase (different concentrations) at different temperatures and time points for pretreatment of the slurry and fermenting the slurry in the presence of the enzymes and proteases such as cellulase to produce the alcohol product is a "the product not of innovation but of ordinary skill and common sense," leading to the conclusion that invention is not patentable as it would have been obvious.

24. Claims 97-98 and 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen (US Patent # 4316956) in view of Katkocin et al (US Patent #4536477).

25. The instant claims are drawn to a process for production of an alcohol product comprising the sequential steps of (a) providing a slurry comprising water and granular starch, holding said slurry in the presence of an acid alpha amylase and a glucoamylase at a temperature of 0°C to 20°C below the initial gelatinization temperature of said granular starch for a period of 20 minutes to 1.5 hours, (b) fermenting the slurry in the presence of an acid alpha amylase and a glucoamylase and a yeast at a temperature between 10°C to 35°C to produce ethanol, recovering the ethanol and the glucoamylase is obtained from a strain of *Aspergillus*, *Talaromyces* or *Clostridium*.

26. As described above in paragraph 8, Lutzen teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). The difference between the reference and the instant claims are that the reference does not teach that the glucoamylase is obtained from a strain of *Aspergillus* (*Aspergillus niger*), *Talaromyces* or *Clostridium*.

27. However, Katkocin et al (US Patent #4536477) teach glucoamylase useful for the hydrolysis of starch (see column 1, lines 6-9). The reference teaches the glucoamylase produced by two new strains of *Clostridium* that were isolated from mud hot springs (see column 2, lines 12-16). The reference further teaches that the thermostability of the purified glucoamylase was compared with that of two other known gulcoamylases.

Results indicate that the glucoamylase from *Clostridium* show superior stability at 70°C

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and pH 5 or 6 over the glucoamylases produced by *Talaromyces duponti* and *Aspergillus niger* (see column 6, lines 52-68).

28. Therefore, it would have been obvious to the ordinary skilled in the art to combine the teachings of Katkocin et al with Lutzen to produce ethanol. There if a reasonable expectation of success since it would be desirable to hydrolyze starch by conducting the liquefaction and saccharification steps simultaneously in the same reaction mixture. This could be accomplished if a glucoamylase were available that would saccharify the liquefied starch at pH values between 6 and 7 where alpha amylase is active. Additionally, the glucoamylase would have to be sufficiently thermostable at this pH to permit the saccharification reaction to be carried out at a temperature where the reaction rate is fast enough to be useful (see Katkocin Patent, column 1, lines 36-45).

Response to Applicant's Arguments

29. Applicant argues that Lutzen does not teach pretreatment step for a period between 20 minutes and 1.5 hours. Katkocin et al do not disclose a process for fermenting granular starch in the presence of an acid alpha-amylase, a glucoamylase and a yeast, as claimed. Moreover, Katkocin et al do not teach or suggest a pretreatment step for a period between 20 minutes and 1.5 hours as claimed.

30. Applicant's arguments have been considered but have not been found persuasive because Lutzen et al disclose the pretreatment steps and teach that temperatures below the initial gelatinization temperature for up to 20 hours will serve to

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hasten the commencement of fermentative generation of ethanol. Furthermore, the Lutzen patent discloses examples of pretreatment at several different time points. Lantero et al teach the process for producing ethanol (commercial fuel alcohol production), using the standard alcohol production steps (liquefaction, saccharification, fermentation, and recovering ethanol). Katkocin et al teach that glucoamylase produced by two new strains of *Clostridium* useful for the hydrolysis of starch (see column 1, lines 6-9). It would have been obvious to try the glucoamylase produced from strains of *Clostridium* since Katocin discloses that the results indicate that the glucoamylase from *Clostridium* show superior stability at 70°C and pH 5 or 6 over the glucoamylases produced by *Talaromyces duponti* and *Aspergillus niger*. Furthermore, the glucoamylase would have to be sufficiently thermostable at this pH to permit the saccharification reaction to be carried out at a temperature where the reaction rate is fast enough to be useful (see Katkocin Patent, column 1, lines 36-45).

31. As described above, it has been held that under KSR that "obvious to try" may be an appropriate test under 103. The Supreme Court stated in KSR, When there is motivation "to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, __82 USPQ2d 1385, 1397 (2007).

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32. The "problem" facing those in the art is described supra. Katkocin et al disclose glucoamylase produced by two new strains of *Clostridium* useful for the hydrolysis of starch (see column 1, lines 6-9). It would have been obvious to try the glucoamylase produced from strains of *Clostridium* since Katocin discloses that the results indicate that the glucoamylase from *Clostridium* show superior stability at 70°C and pH 5 or 6 over the glucoamylases produced by *Talaromyces duponti* and *Aspergillus niger*.

Furthermore, the glucoamylase would have to be sufficiently thermostable at this pH to permit the saccharification reaction to be carried out at a temperature where the reaction rate is fast enough to be useful (see Katkocin Patent, column 1, lines 36-45).

The skilled artisan would have had reason to try these methodologies with the reasonable expectation that at least one would be successful. Different time points for pretreatment, different pretreatment temperatures, different pH and different concentrations of slurry and enzyme would have been tried for production of alcohol.

Thus, holding a slurry of granular starch in the presence of an acid alpha-amylase (different concentrations) and glucoamylase (different concentrations and from different species) at different temperatures and time points for pretreatment of the slurry and fermenting the slurry in the presence of the enzymes to produce the alcohol product is a "the product not of innovation but of ordinary skill and common sense," leading to the conclusion that invention is not patentable as it would have been obvious.

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33. Claims 97-98, 122 and 130-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen (US Patent # 4316956) in view of Veit et al (PG Pub 2004/0091983).

34. The instant claims are drawn to a process for production of an alcohol product comprising the sequential steps of (a) providing a slurry comprising water and granular starch, holding said slurry in the presence of an acid alpha amylase and a glucoamylase at a temperature of 0°C to 20°C below the initial gelatinization temperature of said granular starch for a period of 20 minutes to 1.5 hours, (b) fermenting the slurry in the presence of an acid alpha amylase and a glucoamylase and a yeast at a temperature between 10°C to 35°C to produce ethanol, recovering the ethanol; and the acid alpha-amylase is an alpha-amylase having an amino acid sequence of SEQ ID NO:1. The claim is also drawn to granular starch is obtained from dry milling.

35. As described in paragraph 8, Lutzen teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). The reference does not teach an acid alpha-amylase having an amino acid sequence of SEQ ID NO:1.

36. However, Veit et al (PG Pub 2004/0091983) teach a method of producing ethanol from a starch containing material, comprising steps of (a)-(e) where step (c) discloses liquefaction in the presence of an alpha-amylase having an amino acid sequence SEQ ID NO:1 (see Claim 39). The reference also discloses that milled and liquefied whole grains are also known as mash (see paragraph [0045]). The reference further discloses the thermostable acid alpha-amylases as used herein are the alpha-

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amylase selected from the group *Aspergillus oryzae* and niger derived from *Aspergillus* (see paragraph [0116]). Additionally, the reference discloses that a fermentation process where the starting material is whole grain which have been partitioned into finer parts, preferably by dry milling (see paragraphs [0012], [0026], [0030], [0035] and [0036])

37. Therefore, it would have been obvious to the ordinary skilled in the art to combine the teachings of Lutzen and Veit et al to produce alcohol product. There is a reasonable expectation of success since Veit et al discloses that milled and liquefied whole grain are also known as mash and teaches similar steps of producing ethanol (see Claim 38).

Response to Applicant's Arguments

38. Applicant argues that Lutzen does not teach pretreatment period as claimed. Veit et al does not disclose a process for fermenting granular starch in the presence of an acid alpha-amylase, a glucoamylase and a yeast, and does not teach the pretreatment step for a period of 20 minutes to 1.5 hours.

39. Applicant's arguments have been considered but have not been found persuasive because Lutzen et al disclose the pretreatment steps and teach that temperatures below the initial gelatinization temperature for up to 20 hours will serve to hasten the commencement of fermentative generation of ethanol. Furthermore, the Lutzen patent discloses examples of pretreatment at several different time points. Lantero et al teach the process for producing ethanol (commercial fuel alcohol

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production), using the standard alcohol production steps (liquefaction, saccharification, fermentation, and recovering ethanol). Veit et al teach a method of producing ethanol from a starch containing material, comprising steps of (a)-(e) where step (c) discloses liquefaction in the presence of an alpha-amylase having an amino acid sequence SEQ ID NO:1 (see Claim 39).

40. As described above, it has been held that under KSR that "obvious to try" may be an appropriate test under 103. The Supreme Court stated in KSR, When there is motivation "to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1397 (2007).

41. The "problem" facing those in the art is described supra. Veit et al disclose a method of producing ethanol from a starch containing material, comprising steps of (a)-(e) where step (c) discloses liquefaction in the presence of an alpha-amylase having an amino acid sequence SEQ ID NO:1 (see Claim 39). The skilled artisan would have had reason to try these methodologies with the reasonable expectation that at least one would be successful. Different time points for pretreatment, different pretreatment temperatures, different pH and different concentrations of slurry and enzyme would have been tried for production of alcohol. Thus, holding a slurry of granular starch in the presence of an acid alpha-amylase (different concentrations and different sequences

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such as SEQ ID NO: 1) and glucoamylase (different concentrations and from different species) at different temperatures and time points for pretreatment of the slurry and fermenting the slurry in the presence of the enzymes to produce the alcohol product is a "the product not of innovation but of ordinary skill and common sense," leading to the conclusion that invention is not patentable as it would have been obvious.

42. Claims 97-98 and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen NW (US Patent # 4316956) in view of James et al (US Patent # 3880742).

43. The instant claims are drawn to a process for production of an alcohol product comprising the steps of (a)-(b), wherein step (a) is performed in the presence of an enzyme activity selected from the group consisting of xylanase, cellulase and phytase.

44. As described above in paragraph 8, Lutzen teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). The difference between the reference and the instant claims is that the reference does not teach an enzyme activity of cellulase in step (a).

45. However, James et al (US Patent # 3880742) teach the b-glucan added to the mash should preferably be active in the high temperature stage of alpha-amylase activity following starch liquefaction if optimum β -glucan degradation is to be effected. The β -glucanase enzyme preparations obtained will normally exhibit further forms of

enzymatic activity, including cellulose and alpha-amylase activity (see column 6, lines 53-57 and lines 63-66).

46. Therefore, it would have been obvious to the ordinary skilled in the art to combine the use of enzyme cellulase in step (b), since the *"normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages"*. There is a reasonable expectation of success since James et al teaches that the use of the enzyme preparation in such enzymatic brewing processes has the additional advantage of reducing the quantities of such enzymes to be added separately to the mash.

Response to Applicant's Arguments

47. Applicant argues that Lutzen does not teach the pretreatment step period. James et al disclose a thermostable beta-glucanase and its use in the degradation of glucagan substrates such as barley-containing animal feed components and barley mashes, but do not disclose a process for fermenting granular starch in the presence of alpha-amylase, a glucoamylase and a yeast, and the pretreatment step period.

48. Applicant's arguments have been considered but have not been found persuasive as described above in the Response to Arguments.

49. As described above, it has been held that under KSR that "obvious to try" may be an appropriate test under 103. The Supreme Court stated in KSR, When there is motivation "to solve a problem and there are a finite number of identified, predictable

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solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, ___, 82 USPQ2d 1385, 1397 (2007).

50. The “problem” facing those in the art is described supra. James et al teach the β -glucan added to the mash should preferably be active in the high temperature stage of alpha-amylase activity following starch liquefaction if optimum β -glucan degradation is to be effected. The skilled artisan would have had reason to try these methodologies with the reasonable expectation that at least one would be successful. Different time points for pretreatment, different pretreatment temperatures, different pH and different concentrations of slurry and enzyme would have been tried for production of alcohol. Thus, holding a slurry of granular starch in the presence of an acid alpha-amylase (different concentrations and different sequences) and glucoamylase (different concentrations and from different species) at different temperatures and time points for pretreatment of the slurry and fermenting the slurry in the presence of the enzymes to produce the alcohol product is a “the product not of innovation but of ordinary skill and common sense,” leading to the conclusion that invention is not patentable as it would have been obvious.

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51. Claims 97-98 and 134-135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen NW (US Patent # 4316956) in view of Leach et al (US Patent # 3922196) and in view of Gray et al (Journal of Bacteriology, 1986, 166(2): 635-643).

52. The instant claims are drawn to a process for production of an alcohol product comprising the steps of (a)-(b), wherein the acid alpha-amylase is an acid bacterial alpha-amylase and is derived from a strain of *B. licheniformis*, *B. amyloliquefaciens*, or *B. stearothermophilus* alpha-amylase.

53. As described above in paragraph 8, Lutzen teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). The difference between the reference and the instant claims is that the reference does not teach the acid alpha-amylase is an acid bacterial alpha-amylase and is derived from a strain of *B. licheniformis*, *B. amyloliquefaciens*, or *B. stearothermophilus* alpha-amylase.

54. However, Leach et al (US Patent # 3922196) teach a process for converting granular starch to a soluble hydrolysate comprising agitating a mixture of granular starch, water, and an alpha-amylase and at least one saccharification enzyme at a temperature between the normal initial gelatinization temperature of the starch and the actual gelatinization temperature of the starch (see abstract). The reference further teaches that the granular starch is solubilized with a bacterial alpha-amylase enzyme preparation if a first step which may alternatively include a saccharifying enzyme such as glucoamylase or beta-amylase, and this first step is thereby followed by a saccharification or conversion step (see column 8, lines 12-18). The reference further

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teaches that the preferred sources of alpha-amylases include certain species of *Bacillus* microorganism, viz., *B. subtilis*, *B. licheniformis*, *B. coagulans* and *B. amyloliquefaciens* (see column 3, lines 32-35). The difference between the reference and the instant claim is that the reference does not teach *B. stearothermophilus*.

55. However, Gray et al (Journal of Bacteriology, 1986, 166(2): 635-643) teach that the amylases of *B. licheniformis* and *B. stearothermophilus* are related as indicated by homology at the DNA and protein levels. They belong to an enzyme family with members which also include the amylases of *B. coagulans* and *B. amyloliquefaciens* (see p. 642, Discussion).

56. Therefore, it would have been obvious to the ordinary skilled in the art to use the alpha-amylase from these species *B. licheniformis*, *B. amyloliquefaciens*, or *B. stearothermophilus*. There is a reasonable expectation of success since Gray et al teach that the amylases of *B. licheniformis* and *B. stearothermophilus* are related (see paragraph 46) and transformation of *E. coli* with vectors containing either gene resulted in the synthesis and secretion of active enzymes similar to those produced by the parental organisms (see abstract). Additionally, Leach et al teach that the enzymes from *B. licheniformis* are unusually effective in the liquefaction of granular starch. Since the enzymes are related, it would have been obvious to use alpha-amylase from *B. licheniformis*, *B. amyloliquefaciens*, or *B. stearothermophilus*.

Response to Applicant's Arguments

57. Applicant argues that Lutzen does not teach the time period of pretreatment as claimed. Leach and Gray do not teach a process for fermenting granular starch in the presence of an acid alpha-amylase, a glucoamylase and a yeast at a temperature between 10°C to 35°C. Moreover, Leach and Gray do not teach the pretreatment time period.

58. Applicant's arguments have been considered but have not been found persuasive because as described above in the Response to Applicant's Arguments.

59. As described above, it has been held that under KSR that "obvious to try" may be an appropriate test under 103. The Supreme Court stated in KSR, When there is motivation "to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, __, 82 USPQ2d 1385, 1397 (2007).

60. The "problem" facing those in the art is described supra. James et al teach the β -glucan added to the mash should preferably be active in the high temperature stage of alpha-amylase activity following starch liquefaction if optimum β -glucan degradation is to be effected. The skilled artisan would have had reason to try these methodologies with the reasonable expectation that at least one would be successful. Different time points for pretreatment, different pretreatment temperatures, different pH and different

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concentrations of slurry and enzyme would have been tried for production of alcohol. Thus, holding a slurry of granular starch in the presence of an acid alpha-amylase (different concentrations and different sequences) and glucoamylase (different concentrations and from different species) at different temperatures and time points for pretreatment of the slurry and fermenting the slurry in the presence of the enzymes to produce the alcohol product is a "the product not of innovation but of ordinary skill and common sense," leading to the conclusion that invention is not patentable as it would have been obvious.

New Grounds for Rejection

35 U.S.C. 112, 2nd

61. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

62. Claims 101-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

63. The base claim 97 recites that step (a) is at a temperature of 0°C to 20°C below the initial gelatinization temperature. Claims 101-103 recites temperatures between 45°C to 75°C, 55°C and 65°C and 55°C and 62°C. It is unclear if these temperature ranges recited in claims 101-103 are actual (initial gelatinization) temperature at which reaction (a) is taking place or the temperatures 0°C to 20°C below the initial gelatinization temperature. The specification discloses that the initial gelatinization

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temperature means the lowest temperature at which gelatinization of the starch commences. Starch heated in water begins to gelatinize between 50°C and 75°C (see paragraph [0018]). Since the initial gelatinization occurs between 50°C and 75°C, this implies that 0°C to 20°C below the initial gelatinization temperature would be between 30°C-50°C and 55°C-75°C. The temperatures recited, between 45°C and 55°C, 55°C and 65°C, and 55°C and 62°C, are above the "20°C below the initial gelatinization temperature" (30°C-55°C). Therefore, the claims are indefinite.

Rejection-35 U.S.C. 102

64. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

65. Claims 97-100, 113-116, 119-122, 128-130 and 132-137 are rejected under 35 U.S.C. 102(e) as being anticipated by Grichko V (PG Pub 2004/0063184).

66. The applied reference has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

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the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

67. The instant claims are drawn to a process for production of an alcohol product comprising the sequential steps of: (a) holding a slurry comprising water and granular starch in the presence of an acid alpha-amylase and a glucoamylase at a temperature of 0°C to 20°C below the initial gelatinization temperature of the granular starch for a period between 20 minutes and 1.5 hours, and (b) fermenting the slurry in the presence of an acid alpha-amylase, a glucoamylase and a yeast at a temperature between 10°C to 35°C to produce the alcohol product, and recovering the alcohol product, wherein the alcohol product is fuel ethanol, potable ethanol and/or industrial ethanol, or the alcohol product is a beer.

68. Grichko V teaches (a) treating a granular starch slurry with an acid alpha-amylase and a glucoamylase at a temperature of 0°C to 20°C below the initial gelatinization temperature of the granular starch, preferably for a period of 5 minutes to 12 hours, (b) treating the slurry in the presence of an acid alpha-amylase, glucoamylase, a yeast and at least one esterase at a temperature of between 10°C and 35°C, preferably for a period of 20 to 250 hours to produce ethanol (see paragraph [0081]). The reference further teaches that the following fermentation, the mash may be distilled to extract the alcohol product (ethanol)...fuel ethanol, drinking ethanol (i.e., potable neutral spirit) or industrial ethanol (see paragraph [0087]). Furthermore, the reference teaches that fermentation was completed, beer fraction was withdrawn and analyzed by HPLC (see paragraph [0129]). Furthermore, the reference discloses the pH

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range of step (b) (see paragraph [0086]), where the granular starch is obtained from (see paragraph [0022]), and the species of alpha-amylase and glucoamylase (see for example, paragraph [0026]) and the enzymes claimed (see paragraph [0038]).

Therefore, this meets the limitation of claims 97-100, 113-116, 119-122, 128-130 and 132-137.

Conclusion

69. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). No claims are allowed.

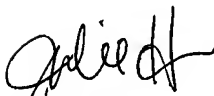
70. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

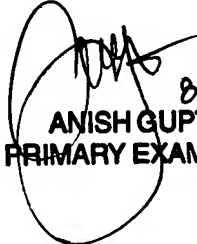
71. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Julie Ha
Patent Examiner
AU1654


8/10/08
ANISH GUPTA
PRIMARY EXAMINER